Remarks

By the foregoing Amendment, claims 1, 5, and 20 have been amended, and new claim 23 has been added. Applicant respectively submits that no new matter has been added by this Amendment and entry and favorable consideration thereof is earnestly requested.

The Examiner has rejected claims 5 and 9 under 35 U.S.C. § 112. Claim 5 has been amended accordingly. The rejection of claim 9, which Applicant believes was directed toward claim 10, is respectfully traversed.

The Examiner has also rejected claims 1, 2-3, 5, 6, 8, 20-22 as unpatentable over U.S. Patent No. 6,241,771 to Gresser et al. ("Gresser") under 35 U.S.C. §§ 102(a), 102(e), and 103(a). The Examiner has rejected claims 1, 2-3, 5, 6, 8, 14, and 20-22 as unpatentable over U.S. Patent No. 6,099,520 to Simonian et al. ("Simonian) under 35 U.S.C. § 102(a), 102(e), and 103(a). The Examiner has rejected claim 20 as unpatentable over U.S. Patent No. 5,941,883 to Jammet et al. ("Jammet") under 35 U.S.C. 103(a). The Examiner has rejected claims 9-11 as unpatentable over Gresser or Simonian under 35 U.S.C. § 103(a). These rejections are respectfully traversed.

35 U.S.C. § 112 rejections

Claim 5

Applicant has amended claim 5 in light of the Examiner's 35 U.S.C. § 112 rejection. It is now dependent on claim 1.

Claims 9/10

Applicant respectfully believes that the Examiner's 35 U.S.C. § 112 rejection of claim 9 was directed at claim 10, because claim 10 and not claim 9 deals with locating the bridge at the head portion. Applicant further respectfully submits that claim 10 is

supported by the specification. The specification teaches, "In a further embodiment, the axial groove, in particular in the head portion, is cross-connected over the circumference with at least one bridge." (Application, p. 6, line 27 – page 7, line 1). Based on this embodiment, claim 10 claims that the bridge "is provided in said head portion of said screw body."

Applicant has also added claim 23, which claims a bridge located at a distal end of the screw body, as supported by the specification in discussing other embodiments of the screw: "Individual or even all of the drive elements can be interconnected at their circumference to avoid a radial spreading. This is indicated in Figs. 2 and 4 with a bridge 56 which cross-connects the drive elements 48, 49, 50 in circumferential direction at the distal end region." (Application, p. 13, line 27 – page 14, line 2).

35 U.S.C. § 102 and §103 rejections

Claim 1

Neither Gresser nor Simonian anticipates claim 1 of the Application under 35 U.S.C. §§ 102(a) or (e), because neither discloses, teaches, or suggests each and every element of claim 1. Further, neither Gresser nor Simonian render claim 1 of the Application obvious under 35 U.S.C. § 103(a), because it would not be obvious to one skilled in the art to modify either Gresser or Simonian to obtain the invention of claim 1.

Gresser

Applicant respectfully submits that Gresser does not anticipate claim 1, because it does not embody an interference screw, five drive elements for inserting into up to five grooves, or a tool for driving in the screw. Further, because it would not be obvious to modify Gresser to embody these elements, Gresser cannot render claim 1 obvious.

Applicant respectfully submits that Gresser is not an interference screw. The Examiner has submitted that the phrase of claim 1, "configured as an interference screw

for anchoring a transplant in an opening in a bone," is functional language. Accordingly, applicant has amended claim 1 to positively recite "an interference screw."

The Examiner has further submitted that the device of Gresser is an interference screw per the present invention. Applicant respectfully disagrees. As defined in the Application, "Interference screws have the purpose of anchoring a tendon or a ligament transplant to a bone. . . . The screw is driven into the intermediate space between the transplant and an inner wall of the channel, so that the transplant is then clamped between the screw and the inner channel wall." (Application, p. 1, lines 11-16). This definition is more specific than that provided by the Examiner ("something that hinders, obstructs, or impedes" (Official Action, p. 3)). Although the Examiner submits that the device of Gresser anchors a transplant in the bone, Gresser is still not an interference screw as defined in the present application. Gresser's device is a "spinal wedge for vertebral spacing" (col. 4, line 65), that is, it fills in the space between adjacent vertebrae in the spine. Gresser teaches creating and filling voids in the screw with "grating material to facilitate bony development" (col. 4, lines 2-3); nowhere however, does Gressor teach anchoring a ligament in a hole in a bone with the tendon in direct contact with the interference screw per the present invention. The present invention teaches placing voids in its screw to allow growth of biological material within the screw. (*See, e.g.,* Application, p. 11, line 20 – p. 12, line 4). Because Gresser does not disclose using the screw to clamp ligament and tendon transplants in place, it therefore does not disclose an "interference screw" as defined in the Application.

Further, Applicant respectfully submits that it would not be obvious to modify Gresser to provide an interference screw. Gresser teaches a device that is designed to go in between vertebrae to fill the gap and to facilitate bone development, which is vastly different from the use of an interference screw. Gresser provides no motivation to drive the screw into bone, and in fact it would be unnecessary to do so, as the device fits into an existing gap between vertebrae, and the surrounding vertebrae anchor the device in place.

As the Examiner notes, Gresser does not explicitly disclose the possibility of having up to five drive elements for inserting into up to five grooves at least partially for aiding in the insertion of the device. Applicant additionally submits that it would not be obvious to one of ordinary skill in the art to modify the Gresser device to embody such drive elements. Rather, Gresser specifically states that the "cylindrical axially extending hole 23 and slots 24," which are in the top of the device of Figures 2A-2C, may be used to "facilitate screwing the device into the spine of the patient." (Col. 4, lines 36-39). The recesses, however, are provided for a vastly different function: "The device also contains recesses 26 between ridges 22 to facilitate ingrowth of tissue that would aid in anchoring the device in place." (Col. 4, lines 39-41). Gresser teaches a central axially extending hole for inserting the screw, and then in the next sentence discloses side recesses for a completely different purpose. There is no motivation to discard the teachings of Gresser in view of the present invention. It is clear that these recesses cannot receive driving elements, and were never intended to be used to aid in screwing in the device. Therefore, it would not be obvious to one of ordinary skill in the art to provide a tool with drive elements to insert into these side grooves, since these side grooves are not for inserting the screw. Thus, Gresser cannot render claim 1 obvious under.

Further, although Applicant agrees with the Examiner that some tool is necessary to insert any screw, as noted by the Examiner, Gresser does not teach a tool for driving in the screw. Therefore, Gresser cannot anticipate claim 1 under 35 U.S.C. §§ 102(a) or (e). This also provides reason to believe that Gresser is not focused on providing a specialized driving method for the screw, so that it would not be obvious to one of ordinary skill in the art to modify Gresser to arrive at claim 1, making claim 1 non-obvious under 35 U.S.C. § 103(a). Applicant repeatedly emphasizes how a special tool is created to match the specific model of screw, for example: "A tool is provided to be <u>exactly adapted</u> to the construction of the respective screw or the configuration of its axial groove." (Application, p. 7, lines 16-18) (emphasis added). See also the language of claim 1, where Applicant affirmatively claims a tool as one of the elements of the

claimed apparatus: "a tool having up to five drive elements for inserting into said up to five grooves." Gresser does not teach a particular method of driving in the device, but rather teaches how the device integrates into the spine.

Applicant respectfully submits that it is improper to use the Application as a road-map for reading into Gresser structure or uses of the grooves not contemplated by Gresser. An important objective of the invention taught in the Application was to remedy the problems inherent in inserting screws using only holes in the top of the screw and/or centrally extending openings. The Application cautions against using "a relatively large and branched central opening, so that only a relatively thin wall remains for the screw body," as this can result in a screw unable to "withstand the high forces applied when driving" it in. (Application, p. 2, line 27 – p. 3, line 4). For biodegradable screws in particular, this "has a disadvantage . . . [in] that when the thin wall of the biodegradable body is biologically degraded after a relatively short time, a large hollow space results" and the screw no longer provides "a sufficient clamping force" to "hold the tendon or ligament transplant in place." (Application, p. 3, lines 6-11). Figures 2A-2C show that Gresser uses a cross-sectional type central opening, the type of opening that the Application, and claim 1 in particular, rejects. Alternatively, Gresser teaches away from using side grooves for inserting the screw, by teaching use of only a center hole. Applicant therefore respectfully submits that Gresser does not render claim 1 obvious under 35 U.S.C. § 103(a).

Simonian

Applicant respectfully submits that Simonian does not anticipate claim 1, because it does not embody a screw or a tool having up to five drive elements for inserting into up to five grooves. Further, it would not be obvious to modify Simonian to embody these elements.

Claim 1 recites a screw. Applicant respectfully submits that Simonian does not teach or disclose a screw, and it would not be obvious to modify the Simonian device to embody a screw. The Simonian device is not a screw because it does not have threads and is not rotationally inserted into an opening. A screw as illustrated and described in the present application is inserted through the use of a rotational motion. The Simonian device is more accurately described as an anchor. Simonian discloses a device that that is inserted "in the bone hole in response to axial motion of the body into the bone hole without requiring further manipulation of the device." (Col. 1, lines 27-30). More specifically, with reference to FIG. 3, a "guidewire is positioned through bone tunnel 18 with the aid of an insertion tool, not shown, located within recess 124. No further manipulation of device 100 is required. For example, neither rotation of the fixation device or insertion of second member to expand the device or wedge the device in place is required to position the fixation device within the bone tunnel." (Col. 4, lines 27-38). Simonian even provides a reason why rotational motion is avoided: having only axial motion "reduc[es] wear on the soft tissue" being fixated. (Col. 2, lines 34-37). Thus, Simonian explicitly teaches away from a screw, and the screw of the Application in particular, which is inserted using rotational motion, and does not render claim 1 obvious under 35 U.S.C. § 103(a).

Simonian further teaches that the grooves cut into the outer side of the body of the soft-tissue fixation device serve for receiving the tissue segments. (Col. 3, lines 17-19 and 32-37; Fig. 1) ("During use, fixation deice 10 is inserted into bone tunnel 18 with soft tissue 12 located with longitudinal channels 24, 26, 28, 30. As shown in FIG. 1, soft tissue 12 includes four tissue segments 44, 46, 48, 50. Each segment is located in one of the four channels.") If a tool with drive element is inserted into the grooves of the soft-tissue fixation device, it would be impossible to additionally insert into these grooves for holding the tissue segments as taught in Simonian. Simonian therefore teaches away from use of the axially extending grooves to screw the device into the bone as such a use as proposed by the examiner would render the device inoperable.

Applicant further respectfully submits that Simonian does not disclose, teach, or suggest "a tool having up to five driving elements for inserting into said up to five grooves." (Application, claim 1). As discussed above, Simonian clearly defines the way the device is inserted, and specifies that no other motion is necessary. Simonian specifies that a driver is inserted into "recess 124" of "proximal end 128." (Col. 4, lines 4-5). On the other hand, the axial "channels (108, 110, 112, 114)" are the site of ribs 130a-130i (col. 4, lines 5-7), which are used to "engage soft tissue 12 located within channels 108, 110, 112, 114 to aid in securing the soft tissue within the channels and thus within bone tunnel." (Col. 4, lines 38-41). The channels cannot be used along with a driving tool to insert the device because axial movement is specifically prohibited per the teachings of Simonian. Further, the fact that the device is inserted with only an axial motion makes moot the reason the Application discloses the side grooves in the first place: using only a "large and branched central opening . . . has the disadvantage . . . that the twist resistance is no longer sufficient to withstand the high forces applied when driving the screw." (Application, p. 2, line 27 – p. 3, line 4). Since Simonian doesn't disclose, teach, or suggest a screw that is inserted through rotational motion, and in fact teaches directly away from such a screw, problems caused by high driving forces when inserting such a screw are irrelevant. It cannot be obvious to one skilled in the art to add these elements when there is no apparent reason to do so based on the teachings of Simonian.

Claim 20

Neither Gresser nor Simonian anticipates claim 20 of the Application under 35 U.S.C. §§ 102(a) or (e), because neither discloses, teaches, or suggests each and every element of claim 1. Further, Gresser, Simonian, or Jammet alone or in any combination fail to render claim 20 of the Application obvious.

Applicant has amended claim 20 to positively recite an "interference screw." Applicant has further amended claim 20 to positively recite a tool to insert into the side grooves.

Gresser/Simonian

As explained in conjunction with claim 1, Applicant respectfully submits that neither Gresser nor Simonian teaches, discloses or suggests an interference screw. Further, neither Gresser nor Simonian teaches, discloses or suggests an insertion tool with a driving element for a side groove as previously stated. Applicant respectfully submits that Claim 20 is not anticipated by or rendered obvious in view of Gresser or Simonian as previously stated in connection with claim 1.

Jammet

Jammet does not disclose, teach, or suggest an interference screw, nor would it be obvious to one skilled in the art to modify Jammet to provide an interference screw. Jammet teaches what is commonly known as a suture anchor, not an interference screw. The Jammet abstract states that the invention is "A medical screw adapted to be anchored in osseous material during surgery to secure a suture." Rather than disclosing an interference screw that is "driven into the intermediate space between the transplant and an inner wall of the channel" (Application, p. 1, lines 14-15), Jammet, with reference to FIGS. 3-4, discloses a screw that is to be "implanted in the osseous material 24, the screw threads 16 penetrating the osseous material in known manner." (Col. 3, lines 9-11). It can be seen from FIG. 4 in particular that the screw is surrounded on all sides by osseous material, rather than, as in the Application, clamping a transplant against the osseous material. In Jammet, the transplant is not anchored in an opening in a bone, rather only the screw is anchored in the bone and then the transplant is anchored to the screw. (FIGS. 7A-7B). Since Jammet is directed toward a suture, and a screw implanted in osseous material, it teaches away from an interference screw, which

has threads in direct contact with the transplant tissue as well as osseous material. There is no motivation to use the clamping method along with Jammet, as the Jammet screw is designed for use with a suture.

Applicant also respectfully submits that it would not be obvious to modify the anchor screw taught in Jammet to comprise not only an interference screw, but one with axially extending grooves. Although Jammet does teach an anchor screw having axially extending grooves to receive a tool (FIGS. 6 and 8), it would not be obvious to use these axially extending grooves if the anchor screw were modified to be an interference screw, as the sheer size and depth of the grooves 118 (FIG. 6) of Jammet are not usable in an interference screw arrangement. Once the tool 110 with protrusions 150 (FIG. 8) is removed, two large axially extending grooves 118 are left in the side of the anchor screw, which would defeat the ability of the screw to exert a clamping force on the transplant. As Jammet is configured as an anchor screw it is unnecessary to exert this lateral clamping force on the ligament to be anchored as per the present invention.

Applicant further respectfully submits that Jammet does not disclose, teach, or suggest using a screw made of biodegradable material, nor it would it be obvious to modify the anchor screw of Jammet to be made of biodegradable material. The screw in Jammet is "made of a light alloy, biocompatible, for example of titanium or titanium alloy." It is evident that "biocompatible" does not mean biodegradable based on the examples. When one considers the function of the device in Jammet, it is evident that using a biodegradable screw would defeat the purpose of the Jammet device. Jammet concerns a "medical screw usable particularly in cosmetic surgery so as to anchor a surgical suture." (Col. 1, lines 12-14). Since the transplant is only connected to the suture, which is in turn connected to the suture anchor screw, any degradation of the suture anchor screw could cause it to come loose from the hole in which it is inserted, thereby causing a failure of the transplant. Alternatively, the interference screw claimed in the Application will eventually biologically degrade, which is highly desireable, because the transplant is inserted into the hollow space in the bone, which will gradually

fill in with new biological material as the interference screw degrades. (Application, page 4, lines 1-11).

Additionally, the Examiner submits that it would be obvious to modify the anchor screw of Jammet to include a taper; Applicant respectfully disagrees. The shaft of the screw in Jammet is "substantially cylindrical," which is necessary to achieve "good penetration of the screw threats into the osseous material" and ensure "excellent anchoring." (Col. 2, lines 65-67; Col. 4, lines 15-19). The tapering as claimed in claim 20 does not engage with the bone as well as a substantially cylindrical shaft member. (See Figures 8 and 9 of the Application). However, tapering is preferable for an interference screw as the screw threads directly engage with the transplant and it is very important that the transplant not become damaged. (Page 16, lines 8-13). Accordingly, applicant submits that Jammet cannot render the present claims obvious.

It is respectfully submitted that claims 1-11, 14, and 20-23, all of the claims remaining in the application, are in order for allowance and early notice to that effect is respectfully requested.

Respectfully submitted,

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